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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,714

10/01/2001

Caroline J. Springer

620-162

7025

7590

07/14/2004

Nixon & Vanderhye

8th Floor

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,714	Applicant(s) SPRINGER ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 103-157 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 103-154 is/are allowed.
- 6) ☒ Claim(s) 155-157 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Final Rejection

The Status of Claims

Claims 103-157 are pending.

Claims 155-157 have been rejected.

Claims 103-154 are allowable.

Claim Rejections - 35 USC § 112

1. Applicants' argument filed 4/27/04 have been fully considered but are persuasive.

The rejection of claims 155-157 under 35 USC § 112, first paragraph has been maintained due to applicants' failure to modify in the amendment.

In the amendment, applicants argue that there is a support for treatment of variety of cancers on page 30, lines 2-13 of the specification.

With respect to applicants' argument, the applicants' specification does not meet the enablement requirement. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

With respect to the state of the prior art, the specification falls short because data essential for treating cancers is not described in the specification. In the absence of specific malignant tumors for example, leukemia, colorectal cancer, ovarian cancer, pancreatic cancer, melanoma, glioblastoma, small cell lung cancer, non-small cell lung cancer, muscle cancer, or prostate cancer, or otherwise, data showing inhibition of the multiplication of cancer cells, such a broad assertion is not believable in view of the contemporary knowledge of the art. 34 USPQ 2d, 1436 (Fed Cir. 1995). See also, MPEP 2107.01, 2107.02, 2107.03, 2164.01©, 2164.04, 2164.07.

Moreover, the claim sets forth the treatment of cancer generally. However, there are more than 3000 cancers. Applicants have not identified a specific compound capable of treating "cancers" broadly. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective anti-tumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, regarding the necessary quantity of experimentation, it is beyond the skill of oncologists today to get an agent to be effective against cancers

generally, evidence that the level of skill in this art is low relative to the difficulty of such a task. See also, *In re Joller*, 206 USPQ 885 (CCPA 1980).

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of Claims 48-55, 66-83, 87-89, 91 and 100-102 under 35 U.S.C. 102(b) as being anticipated clearly by Springer et al (WO94/25429) has been withdrawn due to the cancellation of the claims in the amendment.

2. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Cozzi et al (WO97/03957) has been withdrawn due to the cancellation of the claims in the amendment.

3. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Karpavicius et al (Izvestiya Akademii Nauk SSSSR, 1979, (1), p. 51-8) has been withdrawn due to the cancellation of the claims in the amendment.

4. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Karpavicius et al (Poiski Izuch. Protivopukholevykh, 1977, 66-75) has been withdrawn due to the cancellation of the claims in the amendment.

5. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Ivanova et al (Leikozoologiya, 1975, 4, 23-9) has been withdrawn due to the cancellation of the claims in the amendment.

6. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Prasmickiene et al (Izvestiya Akademii Nauk SSSSR, 1969, (3), p. 643-6) has been withdrawn due to the cancellation of the claims in the amendment.

7. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Jen et al (Huaxue Xuebao, 1965, 31(6), p. 486-92, 500) has been withdrawn due to the cancellation of the claims in the amendment.

8. The rejection of Claims 87-89, and 91 under 35 U.S.C. 102(b) as being anticipated clearly by Davis et al (Journal of the chemical Soc., 1950, p. 1331-7) has been withdrawn due to the cancellation of the claims in the amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

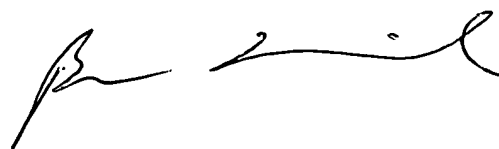
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/11/04



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PRIMARY EXAMINER
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